REMARKS

Reconsideration of the above-referenced patent application is respectfully requested in view of the foregoing amendments and remarks set forth herein.

In the Office Action of **October 7, 2010**, the Examiner took the following actions to which Applicant herein makes response: (1) rejected claims 2-7 and 11 under Section 102(e) as being anticipated by newly cited Connolly et al. (7,105,336); and (2) provisionally rejected claims 2-5 and 7 on the ground of nonstatutory obviousness-type double patenting over claims 1, 2, 5 and 6 of copending SN 11/123,330 (client file BIOA5110). These rejections are traversed in application to the claims as amended, and consideration is requested of the patentability of claims 2-7 and 11 now pending in the pplication.

1) **Rejection of claims 2-7 and 11 under Section 102(e) as being anticipated by newly cited Connolly et al. (7,105,336)**

Claims 2-7 have been cancelled.

Applicant respectfully submits that claim 11, being a claim for a *method* of producing an ingestible product, comprises three steps that are neither taught nor suggested by Connolly et al. Thus, Connolly does not teach or suggest "**determining the cytotoxic activity of strains of *Lactobacillus reuteri* by evaluating supernatants for good toxin binding and a toxin neutralizing effect**, said supernatants obtained from growing each strain of *Lactobacillus reuteri* in suitable host cells" or "**selecting strains of *Lactobacillus reuteri* having a good toxin binding and toxin neutralizing effect**" or "**testing cells of the selected strains of *Lactobacillus reuteri* for immunomodulating activity by testing for an increase in the number of CD4+ lymphocytes in tissue samples from a test mammal to which the strains have been administered** (emphasis added)."

The Examiner states that Connolly teaches an ingestible *product* comprising a strain selected for its immuno-modulating effects (emphasis added). It has to be noted that the criteria of Applicant in the method of the instant invention for the selection are

not the same as in Connolly et al. The CD4+ cell recruitment is not necessarily an inherent feature of all *Lactobacillus*, which improve immune functions in mammals. Applicant has previously patented some *Lactobacillus*, which improve immune function in mammals and that do not act on CD4+ cell recruitment as far as Applicant can determine. Because of Applicant's previous extensive observation of substantial differences in efficacy between strains, Applicant has developed this method to select the most effective strain in recruiting CD4+ cells and neutralizing vero toxins.

Applicant respectfully submits that the **method** of claim 11 is unique and neither taught nor suggested by Connolly, even if it were to be found that a strain selected by Applicant's method had characteristics in strains disclosed in Connolly et al. Connolly teaches nothing about how to select the most suitable strains to produce the ingestible product to be used in improving immune-function in mammals.

Screening probiotics for potential use as immune-modulators or antibacterial agent is a laborious process and includes proof of safety, investigation of potential benefits *in vitro*, proof of survival of the strain in the intestinal tract and proof of efficacy. Also it is recommended to select those bacteria that most effectively enhance the desired response. Characteristics ascribed to a probiotic strain are in general strain specific, and individual strains have to be tested for each property.

No one has described Applicant's method of selection before, and it is neither suggested nor taught by Connolly et al. In the method of the invention in claim 11 herein, the idea of binding/neutralizing toxins is to reduce the immune system being occupied fighting these toxins, at the same time as the CD4 cells are increased, thereby giving an improved immune system, more ready to fight new and various challenges such as bacterial and viral infection. This is neither taught nor suggested by Connolly et al.

Applicant therefore submits that claim 11 is patentable over Connolly et al. under Section 102(e).

2) **Provisional rejection of claims 2-5 and 7 on the ground of nonstatutory obviousness-type double patenting over claims 1, 2, 5 and 6 of copending SN 11/123,330 (client file BIOA5110)**

The rejected claims, claims 2-5 and 7, have been cancelled herein.

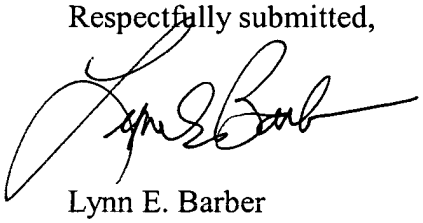
Conclusion

For all the foregoing reasons, claim 11 is submitted to be fully patentably distinguished over the cited references and in allowable condition. Favorable consideration is therefore requested.

Applicant submits that no new claims have been added and therefore that no fee is required for the presentation of this amendment except for the separately submitted fee for extension of time. Any additional amounts that may be due for presentation of this amendment should be charged to Deposit Account No. 02-0825 of Applicant's attorney.

If any questions or issues remain, the resolution of which the Examiner feels would be advanced by a personal or telephonic conference with Applicant's attorney, the Examiner is invited to contact such attorney at the telephone number noted below.

Respectfully submitted,



Lynn E. Barber
Attorney for Applicants
Registration No. 31,734
P.O. Box 16528
Fort Worth, TX 76162
(817) 361-7131

Enclosures:

1) Petition for Extension of Time and Fee
2) Request for Continued Examination and Fee